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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
P-5808/1

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Application Number	Filed
10/664,715	September 18, 2003

First Named Inventor
Dimitrios Manoussakis

Art Unit	Examiner
1797	Patricia Kathryn Wright

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☑ attorney or agent of record.
Registration number 52,515

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

/Mark Lindsey/
Signature

Mark Lindsey
Typed or printed name

201-847-6262
Telephone number

October 29, 2010
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.	10/664,715	Confirmation No.:	4404
Applicant(s)	Dimitrios Manoussakis	Examiner:	P. Kathryn Wright
Filed:	September 18, 2003	Docket:	P-5808/1
Group Art Unit:	1743	Customer No.:	26253

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRESENTATION OF PRE-APPEAL BRIEF REASONS FOR REVIEW

A complete listing of the current pending claims can be found in Applicant's Response dated February 10, 2010 to the Office Action dated August 10, 2009.

Claims Rejections – 35 USC § 103

Claims 14, 16-18, 20-24, 26-28 and 30-32 are rejected under 35 U.S.C. 103(b) as being unpatentable over EP Patent No. 1 107 002 A2 to Hugh Conway ("Conway").

Applicants respectfully traverse this rejection.

Of the claims rejected, claim 14 is independent, with the remaining claims dependent thereon.

Claim 14 recites among other things:

a thixotropic gel in contact with a portion of the inner wall,
wherein the thixotropic gel comprises continuous first and second regions, the first region located at or adjacent to the lower end, and the second region extending upward from a portion of the first region, wherein the first region comprises an imaginary upper boundary at which the first region exhibits 360° circumferential contact with the inner wall, and wherein the first region comprises at least about 80 vol.% of the thixotropic gel.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to

combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants submit that Conway fails to disclose, teach or suggest at least the claimed features of

a) A thixotropic gel in contact with a portion of the inner wall,

b) the first region exhibits 360° circumferential contact with the inner wall, and

c) the first region comprising at least about 80 vol.% of the gel.

Conway teaches a container (tube 12) having an upper end 13 and lower end 14 and a cylindrical wall 15 extending therebetween in which a thixotropic gel 24 is contained within a deformable container or flexible bag 22. Bag 22 is in frictional engagement with the inner surface 15a of cylindrical wall 15 (see Figs. 1 & 2, shown below).

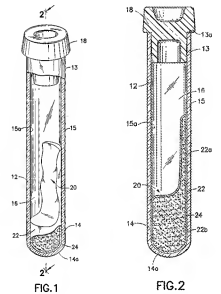

FIG.1 FIG.2

Thus Conway fails to disclose or teach or suggest a container in which the gel is in contact with the inner wall of the container and that the first region (of the gel) exhibits 360° circumferential contact with the inner wall.

The Examiner states in the Office Action dated April 29, 2010:

"Conway does not specifically disclose the gel in contact with a portion of the inner wall of the container. However, the use of thixotropic gel materials as a direct barrier for moving into an area adjacent the two phases of the sample being separated in order to maintain the components separated for subsequent examination of the individual components is well known in the art (see paragraphs [0002]-[0005] of Conway). The thixotropic gels used in separating blood components are typically chemically inert to most analytes present in blood samples. Thus, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to eliminate the flexible bag from the device of Conway since the use of such bags increases the manufacturing cost and complexity of the device."

Applicants respectfully submit that Conway teaches away from the use of a thixotropic gel in direct contact with a blood sample or its separated components (see paragraphs [0004] to [0006] shown below, emphasis added).

[0004] The most widely used device includes thixotropic gel material such as polyester or silicone gels. The present gel serum separation tubes require special manufacturing equipment to prepare the gel and to fill the tubes. Moreover, the shelf-life of the product is limited in that over time unbound resin may be released from the gel mass. This resin may have a specific gravity that is less than or equal to the separated serum and may float in the serum and may clog the measuring instruments such as the instrument probes used during the clinical examination of the sample collected in the tube. Such clogging can lead to considerable downtime for the instrument to remove the clog.

[0005] In addition, no commercially available gel is completely chemically inert to all analytes. If certain drugs are present in a blood sample when it is taken, there can be a chemical reaction at the gel interface.

[0006] Therefore, a need exists for a separator device that (i) is easily used to separate a blood sample; (ii) is independent of temperature during storage and shipping; (iii) is stable with radiation sterilization; (iv) employs the benefits of a thixotropic gel barrier yet avoids the many disadvantages of placing a gel in contact with the separated blood components; (v) minimizes cross contamination of the heavier and lighter phases of the sample; (vi) minimizes entrapment of the lower and higher density materials within the separator device; (vii) is able to move into position to form a barrier in less time than conventional methods and devices; (viii) is able to provide a clearer serum or plasma specimen with less cell contamination than conventional methods and devices; and (ix) can be used with standard sampling equipment.

Therefore one skilled in the art would have no motivation whatsoever to eliminate the flexible bag from the device of Conway.

The Examiner should also note, according to MPEP §2143.01 Section VI, that if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Furthermore, Section V of the MPEP §2143.01 states, that if a proposed modification would render the prior art invention modified unsatisfactory for its intended purpose, then there

is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

The elimination of the flexible bag from the device of Conway results in a change in the principle of operation of the separator as the thixotropic gel contacts the blood and according to the teachings of Conway would render the prior art invention modified unsatisfactory for its intended purpose.

The Examiner further states in the Office Action dated April 29, 2010:

"Conway teaches a thixotropic gel 24 completely contained in deformable container or flexible bag 22. The bag 22 may be formed of materials which sufficient tackiness to promote adherence of the bag to the inner surface 15a of the tube to create first 22b and second 22a continuous regions seen in Figs. 1-3. The first region of the bag and gel is located at or adjacent the lower end 14a and the second region 22a extending upward from a portion of the first region 22b, wherein the first region comprises an imaginary upper boundary at which the first region exhibits 360" circumferential contact with the inner wall 14a, and wherein the first region comprises at least about 80 vol.% of the thixotropic gel. That is, as shown in the Figs. 1 and 2, the gel 24 substantially fills the first portion 22b of the bag 24 with only remaining second portion 22a being substantially absent of gel (see paragraph [0028]). Thus, it can be reasonably assumed that the first region of the gel comprises at least about 80 vol.% of the thixotropic gel."

Applicants submit that Conway fails to disclose, teach or suggest at least the claimed feature of the first region comprising at least about 80 vol.% of the gel.

Conway is completely silent in regard to the vol.% of gel within the first region.

Applicants respectfully disagree with the Examiner's assumptions regarding Conway.

First, Conway does not indicate the drawings (Figs. 1 and 2) were drawn to scale. It is well known that proportions of features in a drawing are not evidence of actual proportions when drawings are not to scale. See MPEP §2125. When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value. It is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.

Second, Conway only discloses that "the gel 24 substantially fills the first portion 22b of the bag 24 with only remaining second portion 22a being substantially absent of gel" (see paragraph [0028]). Thus one skilled in the art cannot reasonably conclude as to what the term "substantially" means in relation to vol.% of gel when no guide or ranges are provided by the disclosure of Conway.

Applicants respectfully submit that Conway fails to teach or suggest a container having a thixotropic gel in contact with a portion of the inner wall, wherein the first region exhibits 360°

circumferential contact with the inner wall, and the first region comprising at least about 80 vol.% of the gel.

For these reasons, applicants submit that independent claim 14 and dependent claims 16-18 20-24, 26-28 and 30-32, are patentable over the Conway reference.

Conclusion

In view of the remarks herein, applicants submit the claims are patentably distinct over the prior art and allowable in form.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 02-1666.

If the Examiner has any questions or comments relating to the present application, he or she is respectfully invited to contact applicants' agent at the telephone number set forth below.

Respectfully submitted,

/Mark Lindsey/

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Dated: October 29, 2010.
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